

CLAIMS:

1. A microneedle device comprising:
a substrate comprising a first major surface;
5 at least one microneedle projecting from the first major surface of the substrate, the at least one microneedle comprising a base proximate the first major surface of the substrate and a tip distal from the base;
a cover comprising a first side facing the first major surface of the substrate and a second side facing away from the substrate, wherein the at least
10 one microneedle penetrates through the first side and the second side of the cover; and
a capillary volume located between the first major surface of the substrate and the first side of the cover; wherein the capillary volume contacts at least a portion of the base of the at least one microneedle.
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2. A device according to claim 1, wherein the at least one microneedle comprises a plurality of microneedles.
3. A device according to claim 1, wherein the cover comprises a liquid
20 impermeable film.
4. A device according to claim 1, wherein the capillary volume comprises conduit structures formed by the substrate.
- 25 5. A device according to claim 1, further comprising standoff structure located within the capillary volume, the standoff structure at least partially defining the capillary volume.
6. A device according to claim 5, wherein the standoff structure defines
30 directional channels extending in at least one selected direction.

7. A device according to claim 1, further comprising standoff structure located within the capillary volume, the standoff structure at least partially defining the capillary volume, wherein the standoff structure protrudes from the first major surface of the substrate.

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8. A device according to claim 1, further comprising standoff structure located within the capillary volume, the standoff structure at least partially defining the capillary volume, wherein the standoff structure protrudes from the first side of the substrate.

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9. A device according to claim 1, further comprising standoff structure located within the capillary volume, the standoff structure at least partially defining the capillary volume, wherein the standoff structure comprises a porous layer with the capillary volume being substantially located within the porous structure.

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10. A device according to claim 1, further comprising a hydrophilic surface within the capillary volume.

20 11. A device according to claim 10, wherein the hydrophilic surface comprises a coating.

12. A device according to claim 1, further comprising a channel formed in an outer surface of the at least one microneedle, the channel extending from the base towards the tip of the at least one microneedle.

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13. A device according to claim 12, wherein the channel is in fluid communication with the capillary volume.

30 14. A device according to claim 1, further comprising a sensor element in fluid communication with the capillary volume.

15. A device according to claim 14, further comprising an electrically conductive pattern, wherein a portion of the electrically conductive pattern is in contact with the sensor element.

5 16. A device according to claim 1, further comprising a glucose test element in fluid communication with the capillary volume, wherein the device further comprises an electrically conductive pattern comprising an anode and a cathode in contact with the glucose test element.

10 17. A device according to claim 1, further comprising sealing adhesive on the second side of the cover.

15 18. A device according to claim 1, wherein the cover extends outside of a periphery of the substrate, and wherein the device further comprises a backing attached to the first side of the cover outside of the periphery of the substrate, wherein the substrate is located between the cover and the backing.

20 19. A device according to claim 18, wherein the substrate comprises a second major surface facing the backing, and wherein the backing is attached to the second major surface of the substrate.

20. A device according to claim 18, wherein the backing is adhesively attached to the first side of the cover outside of the periphery of the substrate.

25 21. A device according to claim 18, wherein the backing is thermally bonded to the first side of the cover outside of the periphery of the substrate.

30 22. A device according to claim 1, wherein the substrate comprises a second major surface facing a housing that is attached to the substrate, wherein a reservoir volume is located between the housing and the substrate, and further wherein the substrate comprises at least one void formed through the first and second major surfaces of the substrate.

23. A microneedle device comprising:
 - a substrate comprising a first major surface and a second major surface;
 - at least one microneedle projecting from the first major surface of the substrate, the at least one microneedle comprising a base proximate the first
 - 5 major surface of the substrate and a tip distal from the base;
 - a cover comprising a first side facing the first major surface of the substrate and a second side facing away from the substrate, wherein the at least one microneedle penetrates through the first side and the second side of the cover;
 - 10 a capillary volume located between the first major surface of the substrate and the first side of the cover; wherein the capillary volume contacts at least a portion of the base of the at least one microneedle;
 - a backing proximate the second major surface of the substrate, wherein the backing extends past a periphery of the substrate; and
 - 15 a cap attached to the backing around the periphery of the substrate, wherein the first major surface of the substrate faces the cap, and wherein the substrate and the at least one microneedle are enclosed between the backing and the cap.
- 20 24. A device according to claim 23, wherein the at least one microneedle comprises a plurality of microneedles.
- 25 25. A device according to claim 23, wherein the cover comprises a liquid impermeable film.
26. A device according to claim 23, wherein the cap is adhesively attached to the backing outside of the periphery of the substrate.
27. A device according to claim 23, wherein the cap is thermally bonded to
- 30 the backing outside of the periphery of the substrate.

28. A device according to claim 23, wherein the backing and the cap comprise a moisture-impermeable package enclosing the substrate and the at least one microneedle.

5 29. A device according to claim 23, wherein the backing is adhesively attached to the first side of the cover outside of the periphery of the substrate.

30. A device according to claim 23, wherein the cover extends outside of the periphery of the substrate, and wherein the backing is attached to the first side of
10 the cover outside of the periphery of the substrate, wherein the substrate is located between the cover and the backing.

31. A device according to claim 30, wherein the backing is adhesively attached to the first side of the cover outside of the periphery of the substrate.

15 32. A device according to claim 30, wherein the backing is thermally bonded to the first side of the cover outside of the periphery of the substrate.

33. A device according to claim 23, further comprising a sensor element in
20 fluid communication with the capillary volume.

34. A device according to claim 33, further comprising an electrically conductive pattern, wherein a portion of the electrically conductive pattern is in contact with the sensor element.

25 35. A device according to claim 23, further comprising a glucose test element in fluid communication with the capillary volume, wherein the device further comprises an electrically conductive pattern comprising an anode and a cathode in contact with the glucose test element.

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36. A method of manufacturing a microneedle device comprising:
providing a substrate comprising a first major surface and at least one
microneedle projecting from the first major surface of the substrate, the at least
one microneedle comprising a base proximate the first major surface of the
5 substrate and a tip distal from the base;
providing a cover comprising a first side facing the first major surface of
the substrate;
forcing the tip of the at least one microneedle through the cover; and
forming a capillary volume located between the first major surface of the
10 substrate and the first side of the cover; wherein the capillary volume contacts at
least a portion of the base of the at least one microneedle.
37. A method according to claim 36, wherein the at least one microneedle
comprises a plurality of microneedles, and wherein tips on the plurality of
15 microneedles are forced through the cover.
38. A method according to claim 36, further comprising applying ultrasonic
energy to the substrate while forcing the tip of the at least one microneedle
through the cover film.
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39. A method according to claim 36, wherein forcing the tip of the at least
one microneedle through the cover film further comprises forcing the tip of the
at least one microneedle into a resilient surface.
- 25 40. A method according to claim 36, further comprising applying ultrasonic
energy to the substrate while forcing the tip of the at least one microneedle
through the cover film, and wherein forcing the tip of the at least one
microneedle through the cover film further comprises forcing the tip of the at
least one microneedle into a resilient surface.
- 30 41. A method according to claim 36, wherein the cover comprises a liquid
impermeable film.

42. A method according to claim 36, wherein the cover comprises a polymeric film.

5 43. A method according to claim 36, wherein the capillary volume comprises conduit structures formed by the substrate.

44. A method according to claim 36, further comprising standoff structure located within the capillary volume, the standoff structure at least partially
10 defining the capillary volume.

45. A method according to claim 44, wherein the standoff structure defines directional channels extending in at least one selected direction.

15 46. A method according to claim 36, further comprising standoff structure located within the capillary volume, the standoff structure at least partially defining the capillary volume, wherein the standoff structure protrudes from the first major surface of the substrate.

20 47. A method according to claim 36, further comprising standoff structure located within the capillary volume, the standoff structure at least partially defining the capillary volume, wherein the standoff structure protrudes from the first side of the substrate.

25 48. A method according to claim 36, further comprising providing a porous layer within the capillary volume, wherein the capillary volume is substantially located within the porous structure.

49. A method according to claim 36, further comprising providing a
30 hydrophilic surface within the capillary volume.

50. A method according to claim 49, wherein the hydrophilic surface comprises a coating.

51. A method according to claim 36, further comprising a channel formed in
5 an outer surface of the at least one microneedle, the channel extending from the base towards the tip of the at least one microneedle.

52. A method according to claim 51, wherein the channel is in fluid communication with the capillary volume.

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53. A method according to claim 36, further comprising providing a sensor element in fluid communication with the capillary volume.

54. A method according to claim 53, further comprising providing an
15 electrically conductive pattern, wherein a portion of the electrically conductive pattern is in contact with the sensor element.

55. A method according to claim 36, further comprising providing a glucose test element in fluid communication with the capillary volume, wherein the
20 method further comprises providing an electrically conductive pattern comprising an anode and a cathode in contact with the glucose test element.

56. A method according to claim 36, further comprising providing an adhesive layer on the second side of the cover.

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57. A method according to claim 36, wherein the cover extends outside of a periphery of the substrate, and wherein the method further comprises attaching a backing to the first side of the cover outside of the periphery of the substrate, wherein the substrate is located between the cover and the backing.

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58. A method according to claim 57, wherein the substrate comprises a second major surface facing the backing, and wherein the method comprises attaching the backing to the second major surface of the substrate.

5 59. A method according to claim 57, wherein the backing is adhesively attached to the first side of the cover outside of the periphery of the substrate.

60. A method according to claim 57, wherein the backing is thermally bonded to the first side of the cover outside of the periphery of the substrate.

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61. A method according to claim 36, further comprising enclosing the substrate and the at least one microneedle by:

providing a backing proximate the second major surface of the substrate, wherein the backing extends past a periphery of the substrate; and

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attaching a cap to the backing around the periphery of the substrate, wherein the first major surface of the substrate faces the cap.

62. A method according to claim 61, wherein the backing and the cap comprise a moisture-impermeable package enclosing the substrate and the at
20 least one microneedle.